UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI

PATRICK & VIRGINIA NARENS,
RILDA LUJAN, JOHN PURDELL,
JANELLE FLOYD, MICHAEL EDWARDS
ROGER GONZALES, MIAVIA COOPER,
PATRICIA & GLENN WILLIAMS

PLAINTIFFS,

v.

3M COMPANY and ARIZANT
HEALTHCARE, INC.

DEFENDANTS

COMPLAINT AND
JURY DEMAND

COMPLAINT AND JURY DEMAND

Plaintiffs, by and through the undersigned and their individual counsel, bring this Complaint to set forth potential claims that individual Plaintiffs may assert against Defendants 3M Company and Arizant Healthcare, Inc. (collectively, “Defendants”), and allege as follows.

INTRODUCTION

1. This is an action for damages relating to Defendants’ design, development, testing, manufacturing, packaging, promoting, marketing, distribution, leasing, supplying, and/or selling of the Bair Hugger Forced Air Warming device (hereinafter “Bair Hugger”).

2. Defendants and their predecessors in interests have designed, developed, tested, manufactured, packaged, promoted, marketed, distributed, supplied, leased, and/or sold the Bair Hugger for well over 30 years. To this day, tens of thousands of patients in hospitals all across the United States undergo surgery each month involving intraoperative use of the Bair Hugger.

3. The Bair Hugger consists of a portable heater or blower connected by a flexible hose to a disposable blanket that is placed over (or in some cases under) surgical patients. The Bair Hugger intakes air from the surrounding area (often from the non-sterile floor of the operating room) and passes it through the intake filter and internal air pathways of the machine and into an outlet hose. The warm air travels through the distal end hose, which does not have an air filter, and into the blanket, which has different compartments through which the warm air moves. The warm air exits the blanket through multiple holes over a patient's exposed skin, providing warmth to the patient during surgery.

4. While warm air accumulates under the surgical drape covering the patient, the air escapes from multiple places. The escaped air creates airflow and/or convection currents that push against and disrupt the downward airflow of the operating theater.

5. Scientific studies have shown that as this warmed air rises against the downward airflow in the operating room, it deposits bacteria from the non-sterile portions of the operating theater to the surgical site.

6. Scientific studies have also shown that the inadequate air filtration system of the Bair Hugger allows pathogenic-carrying cells, including but not limited to isolates of S aureus, coagulase-negative staphylococci ("CoNS"), and methicillin-resistant

staphylococcus aureus ("MRSA"), to penetrate the intake filter of the device and colonize inside the device.

7. Indeed, as the device sits on or near the floor of the operating theater, often directly next to the operating table, it intakes large quantities of desquamated skin cells and other viable microorganisms that have been pushed down to the non-sterile floor of the operating theater. In some cases, these microorganisms move through the intake filter and attach to the inner pathways of the device; in other cases, they enter through gaps between the filter and the device or between the distal end hose and the device. Because the internal air path surfaces of the device cannot be easily cleaned or decontaminated, and the operating instructions for the device do not provide a method for cleaning or decontaminating the inside of the device, microorganisms build up and colonize therein. Without an adequate filtration system at the distal hose outlet, the device releases contaminants into the operating theater and directly onto the surgical site itself.

8. For over two decades, Defendants have known that the Bair Hugger emits significant levels of internally generated airborne contaminants into the operating theater and that the exhaust generated thereby creates convective airflow patterns that disrupt the unidirectional airflow of the operating theater, dramatically increasing the risk of infection for patients undergoing lengthy surgeries, especially hip and knee replacement surgeries.

9. In June 1997, in sworn filings submitted to the Food and Drug Administration ("FDA") in connection with Section 510k of the Food and Drug Act, Defendants

admitted that "[a]irborne contamination from air blown intra-operatively across the surgical wound may result in airborne contamination."[1]

10. Notwithstanding their knowledge of that risk and the availability of safer alternative designs, Defendants actively and aggressively marketed the Bair Hugger as safe in both general and orthopedic surgeries.

11. Defendants also misrepresented that the air filtration system of the Bair Hugger satisfied High Efficiency Particulate Air ("HEPA") standards.

12. Though Defendants touted the Bair Hugger as HEPA compliant to healthcare providers and informed the FDA of the same, the Bair Hugger has never met that standard.

13. Upon information and belief, at some point between 2002 and 2009, Defendants significantly reduced the efficiency of the Bair Hugger's air filtration system.

14. As a result of that decision, the internal airflow pathways of the Bair Hugger become contaminated with pathogens, including isolates of CoNS, mold, and other bacteria, which incubate and proliferate therein. And since the defective design of the device does not include an outlet filter—let alone a HEPA-complaint filter, the Bair Hugger releases contaminants into the operating theater and onto the surgical site.

15. Upon information and belief, Defendants have been aware of the pathogenic contamination of the internal airflow pathways of the Bair Hugger since at least as early as 2009.

[1] See 510(k) Summary of Safety & Effectiveness for the Bair Hugger Patient Warming System, Model 525 Blanket (K903360) (June 26, 1997), https://www.accessdata.fda.gov/cdrh_docs/pdf/K964673.pdf.

16. Contemporaneous publication of scientific studies identifying these issues and the availability of alterative designs should have prompted Defendants to discontinue marketing and selling the Bair Hugger until they could redesign the device to prevent the spread of bacterial contamination.

17. At a minimum, Defendants should have warned patients and healthcare providers of the known risk inherent in using the Bair Hugger in orthopedic surgeries.

18. Instead, amid rising criticism of the Bair Hugger among the medical community, Defendants callously and with conscious disregard of patient safety chose to amplify their efforts to champion the device and silence critics.

19. In fact, Defendants have taken every step imaginable to conceal and discredit peer-reviewed scientific studies that undermine their ability to market the Bair Hugger.

20. Because of Defendants' actions and inactions, Plaintiffs were injured due to the use of the Bair Hugger, which has caused and will continue to cause bacteria to enter the surgical site, resulting in a dramatic increase in the rate of periprosthetic joint infections among all patient populations. These infections have caused Plaintiffs surgical debridement, premature prosthetic replacement, extended hospital stays, and amputations.

21. Plaintiffs therefore demand judgment against Defendants and request, among other things, compensatory damages, statutory damages, attorneys' fees, and costs.

PLAINTIFF-SPECIFIC ALLEGATIONS

22. PATRICK NARENS and Consortium Plaintiff VIRGINIA NARENS at all times relevant hereto, are citizens and residents of Jefferson County, Missouri.

    a. On or about March 5, 2012 the Bair Hugger was used on Plaintiff during the course of Plaintiff's total left hip replacement surgery.

    b. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, resulting in an infection.

    c. Due to the infection, Plaintiff has suffered severe and ongoing injuries, and Plaintiff continues to suffer substantial damages, including but not limited to, impaired mobility.

23. Plaintiff RILDA LUJAN at all times relevant hereto, is a citizen and resident of Clay County, Missouri.

    a. On or about December 3, 2011, the Bair Hugger was used on Plaintiff during the course of Plaintiff's left partial hip replacement surgery.

    b. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, resulting in an infection.

    c. Due to the infection, Plaintiff has suffered severe and ongoing injuries, and Plaintiff continues to suffer substantial damages, including but not limited to, impaired mobility.

24. Plaintiff JOHN PURDELL at all times relevant hereto, is a citizen and resident of Phelps County, Missouri.

    a. On or about August 19, 2011, the Bair Hugger was used on Plaintiff during the course of Plaintiff's total left knee replacement surgery.

b. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, resulting in an infection.

c. Due to the infection, Plaintiff has suffered severe and ongoing injuries, and Plaintiff continues to suffer substantial damages, including but not limited to, impaired mobility.

25. Plaintiff JANELLE FLOYD at all times relevant hereto, is a citizen and resident of Johnson County, Kansas.

a. On or about December 26, 2014, the Bair Hugger was used on Plaintiff during the course of Plaintiff's partial right hip replacement surgery.

b. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, resulting in an infection.

c. Due to the infection, Plaintiff has suffered severe and ongoing injuries, and Plaintiff continues to suffer substantial damages, including but not limited to, impaired mobility.

26. Plaintiff MICHAEL EDWARDS at all times relevant hereto, is a citizen and resident of Lucas County, Ohio.

a. On or about December 11, 2014, the Bair Hugger was used on Plaintiff during the course of Plaintiff's left total knee replacement surgery.

b. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, resulting in an infection.

c. Due to the infection, Plaintiff has suffered severe and ongoing injuries, and Plaintiff continues to suffer substantial damages, including but not limited to, impaired mobility.

27. Plaintiff ROGER GONZALES at all times relevant hereto, is a citizen and resident of Bexar County, Texas.

    a. On or about November 18, 2014, the Bair Hugger was used on Plaintiff during the course of Plaintiff's total left hip replacement surgery.

    b. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, resulting in an infection.

    c. Due to the infection, Plaintiff has suffered severe and ongoing injuries, and Plaintiff continues to suffer substantial damages, including but not limited to, impaired mobility.

28. PATRICIA WILLIAMS and Consortium Plaintiff GLENN WILLIAMS at all times relevant hereto, are citizens and residents of Harris County, Texas.

    a. On or about December 3, 2014, the Bair Hugger was used on Plaintiff during the course of Plaintiff's total left knee replacement surgery.

    b. Because the Bair Hugger was used, contaminants were introduced to Plaintiff's open surgical wound, resulting in an infection.

    c. Due to the infection, Plaintiff has suffered severe and ongoing injuries, and Plaintiff continues to suffer substantial damages, including but not limited to, impaired mobility.

29. Plaintiff MIAVIA COOPER at all times relevant here to is a citizen and resident of Harris County, Texas.

    a. On or about December 2, 2014, the Bair Hugger was used on Plaintiff during the course of Plaintiff's total right knee replacement surgery.

    b. Because the Bair Hugger was used, contaminants were introduced to

Plaintiff's open surgical wound, resulting in an infection.

c. Due to the infection, Plaintiff has suffered severe and ongoing injuries, and Plaintiff continues to suffer substantial damages, including but not limited to, impaired mobility.

PARTIES

30. Plaintiffs are citizens and/or residents of the United States who experienced severe medical complications, injuries, and damages from the use of the Bair Hugger.

31. Defendant 3M Company ("3M") is a corporation organized and existing under the laws of Delaware, with its principal place of business in Maplewood, Minnesota. 3M is engaged in the business of researching, developing, designing, licensing, manufacturing, distributing, leasing, supplying, selling, marketing, and introducing into interstate commerce, either directly or indirectly, products such as the Bair Hugger.

32. Defendant Arizant Healthcare, Inc. ("Arizant") is a corporation organized and existing under the laws of Delaware. Arizant is a wholly owned subsidiary of 3M and conducts business throughout the United States.

33. Prior to 3M's purchase of Arizant for $810 million in 2010, Arizant was known as Augustine BioMedical, Inc.

34. In 1998, Augustine BioMedical, Inc. received 510k clearance to market the Bair Hugger 505.

35. Two years later, the company received 510k clearance to market the Bair Hugger 750.

36. At all times mentioned herein, the employees of Defendants, their subsidiaries, predecessors in interest, affiliates, and other related entities, as well as the employees of each of the individual Defendants' subsidiaries, predecessors in interest, affiliates, and other related entities, were the agents, servants, and employees of Defendants and were acting within the purpose and scope of said agency and employment. Whenever reference is made to any act or transaction of Defendants, such designations shall be deemed to mean that the principals, officers, employees, agents, and/or representatives of Defendants committed, knew of, performed, authorized, ratified, and/or directed such transactions on behalf of Defendants while they were actively engaged in the scope of their duties.

JURISDICTION AND VENUE

37. This Court has jurisdiction pursuant to 28 U.S.C. § 1332(a) because the parties are citizens of different States and the amount in controversy exceeds the sum or value of $75,000, exclusive of interests and costs.

38. Defendants are subject to the in personam jurisdiction of this Court, and venue is proper in this judicial district pursuant to 28 U.S.C. § 1391, as a substantial number of the events, actions, or omissions giving rise to Plaintiffs' claims occurred in this district, and at all times relevant to this matter, Defendants conducted substantial business in this judicial district. Defendants did (and continue to do) business within the state of Missouri and have substantial, continuous, and systematic contacts with the state of Missouri. Defendants have consented to jurisdiction in the state of Missouri and/or committed torts in whole or in part in the state of Missouri and many other states, against thousands of Plaintiffs, as more fully set forth below. On

information and belief, Defendants have marketed, advertised, and sold the Bair Hugger in the Eastern District of Missouri, along with many other judicial districts. They have also made material omissions and representations in each of those judicial districts and breached warranties in each of those judicial districts.

FACTUAL BACKGROUND

39. The Bair Hugger was developed by Augustine Medical, Inc., the corporate predecessor to Arizant, in the mid-1980s.

40. When Augustine Medical, Inc. reorganized in or around 2003, the division of the company that retained the Bair Hugger product line became Arizant.

41. In 2004, Citigroup Venture Capital purchased Arizant for $225 million.

42. In 2010, 3M purchased Arizant and all rights to the Bair Hugger product line for $810 million.

43. Defendants and their predecessors in interest have designed, developed, tested, packaged, manufactured, promoted, marketed, distributed, leased, supplied, and/or sold a variety of Bair Hugger models, including but not limited to the Bair Hugger 505, 750, and 775.

44. More than 50,000 Bair Hugger units are currently in use across the country.

45. Some of the Bair Hugger models cover only a portion of the patient's body; others cover the patient's entire body. Still others are used under a patient's body in order to allow physicians full access to the patient during surgery.

46. Despite those differences, all Bair Hugger models consist of a portable temperature management unit and a disposable blanket. Every model also includes a distal end hose that not only accumulates and allows bacteria to proliferate therein, but blows

hot air and contaminants into the blanket, over the patient's skin, and into the operating environment.

47. Defendants marketed the Bair Hugger to healthcare providers as being able to "meet [their] every day and specialized patient warming needs—from pediatric to geriatric [and] from brief outpatient procedures to long complex procedures."[2]

48. Defendants therefore advertised the Bair Hugger as a suitable forced air warming device for use by all patients, regardless of their medical needs or background.

49. After all, the Bar Hugger's marketing slogan once stated, "Everyone Deserves a Hugg,"[3] even though the device is neither safe nor effective for use in general or orthopedic surgeries.

50. The Bair Hugger produces hot air that builds up in areas around the patient, particularly under the surgical drape covering the patient. Not all of the hot air produced by the Bair Hugger remains there, however. Much of the hot air escapes from under the surgical drape below the level of the surgical table or at the head end of the surgical table. The escaped air then creates convection currents that flow against the downward airflow of the operating theatre. As this warmed air rises, it deposits bacteria and other dangerous pathogens from the non-sterile floor of the operating theater directly to the surgical site.

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[2] See, e.g., 3M Company, http://solutions.3m.com/wps/portal/3M/en_EU/Healthcare-Europe/EU-Home/Products/InfectionPrevention/Patient_Warming/Bair_Hugger_Ther apy/Blankets/ (last visited April 27, 2016).

[3] See, e.g., 3M Company, Bair Hugger Therapy 700 Series Temperature Management Unit, Troubleshooting Guide, http://multimedia.3m.com/mws/media/798477O/model- 700-troubleshooting-guide-english.pdf (last visited April 27, 2016).

51. These bacteria, including but not limited to staphylococcus aureus, CoNS, and MRSA, can and do lead to deep joint or "periproshetic joint infections" for all types of patient populations, including Plaintiffs herein.

52. What's more, the Bair Hugger itself generates airborne contamination that significantly increases the risk of infection for patients undergoing surgeries of all kinds.

53. In a communication to the FDA in July 2000, Defendants asserted that the Bair Hugger's filtration system satisfied HEPA standards. That statement could not have been further from the truth. To qualify as HEPA complaint, an air filter must remove at least 99.97% of all particles 0.3 micrometers or larger from the air that passes through it.

54. Though Defendants marketed and continue to market the Bair Hugger as HEPA complaint, it removes no more than 63.8% of particles 0.3 micrometers or larger.[4]

55. Leaks on the intake side of the device and inadequate air intake filtration can and do lead to buildup of microbial contamination in the internal passageways of the device and adjoining hose. At least one scientific study has revealed the presence of viable microorganisms in 100% of Bair Hugger devices, with the heaviest growth reported on the internal air path surfaces of the "elbow" of the device. Isolates of CoNS, mold, and micrococci were detected inside 74%, 26%, and 9% of Bair Hugger blowers, respectively.[5]

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[4] See, e.g., Reed, M., et al. Forced-Air Warming Design: Evaluation of Intake Filtration, Internal Microbial Buildup, and Airborne-Contamination Emissions. Am Assoc Nurse Anesth J 2013;81:275-80.

[5] See id.

56. Because much of the buildup occurs on inaccessible internal pathways of the device that cannot be easily cleaned, decontaminated, or replaced, the Bair Hugger generates significant levels of airborne contamination downstream of its intake filter.

57. One scientific study concluded that the Bair Hugger emits up to 35,000 particles per cubic foot downstream of its intake filter; [6] another study found that the device releases up to 110,000 particles per cubic foot downstream of its filter, which translates to more than 80,000 particles per second being emitted from the distal end hose of the device.[7]

58. After those particles and other bacteria are expelled from the interior of the Bair Hugger by an outward airflow, they travel into the warming blanket, escape from the holes in the blanket, and land directly onto the surgical site, thereby infecting patients.

59. Upon information and belief, Defendants have known for nearly two decades that the Bair Hugger's inadequate air filtration system and its tendency to disrupt convention currents in the operating theater increase the risk of surgical site and deep joint infections.

60. Notwithstanding their knowledge of those risks and the availability of safer alternative designs, Defendants have continued to market the Bair Hugger to consumers and healthcare providers and to misrepresent the safety of the device in their advertisements, statements to healthcare providers, and submissions to the FDA.

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[6] See Albrecht, M., et al. Forced-Air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. Am J Infect Control 2011;39:321-28.

[7] See Reed, M., et al. Forced-Air Warming Design: Evaluation of Intake Filtration, Internal Microbial Buildup, and Airborne-Contamination Emissions. Am Assoc Nurse Anesth J 2013;81:275-80.

61. In a June 1997 letter to the FDA, for example, Defendants admitted that "air blown intraoperatively across the surgical wound may result in airborne contamination."[8]

62. Defendants addressed that fundamental flaw in the Bair Hugger by making additional misrepresentations to the FDA. Defendants informed the FDA that they had remediated that particular flaw by employing a tape barrier in all Bair Hugger models and that such a barrier would "prevent air from migrating toward the surgical site."[9]

63. That statement was false and misleading, and it remains uncorrected to this very day. Not only are many Bair Hugger models not equipped with a taped edge at all, but even the use of a taped edge cannot prevent hot air from migrating up from the non-sterile floor of the operating theater. The cooler downward airflow in the operating theater causes the hot air from the Bair Hugger to rise upward and move toward the surgical site. The presence of a tape barrier thus does not prevent the Bair Hugger from facilitating the movement of bacteria from the floor of the operating theater to the surgical site. Nor have Defendants done anything to remediate the inadequate air filtration system of the device.

64. Defendants' misrepresentations did not stop with the FDA. For many years, Defendants' website, www.fawfacts.com/laminar_airflow/ (last visited January 20, 2016), contained a multitude of additional misrepresentations, including but not limited to:

   a. Contamination mobilized by the convection currents generated by the Bair Hugger cannot reach the surgical site because "[a]ir velocity within the operating room is many times stronger than that of a forced-air warming blanket";

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[8] See 510(k) Summary of Safety & Effectiveness for the Bair Hugger Patient Warming System, Model 525 Blanket (K903360) (June 26, 1997),

[9] See id.

b. "The air emerging from the blanket is directed downward by the surgical drape and emerges under the operating room table and is drawn away through the laminar system's return air inlets";

c. "It's been suggested that warm air rising above the Bair Hugger blanket could interfere with the downward laminar flow toward the surgical site. It should be noted that the Bair Hugger warming unit delivers less than one percent of the airflow of a laminar flow system and the momentum of the downward air is far greater than the upward momentum imparted to the air above the blanket."

65. The statements in the preceding paragraph are false and intentionally misleading. Through those statements, Defendants disguised the fact that the issue is not the strength of the airflow in a unidirectional system but the heat of the air generated by the Bair Hugger. The cold air circulated within the operating room, having a higher density than the air heated by the Bair Hugger, falls to the floor and forces the contaminated air, now warmed by the waste heat from the Bair Hugger, to enter the sterile field. Accordingly, the hot air is not "drawn away" from the surgical site as Defendants maintain.

66. Moreover, in a marketing video produced by Defendants, previously available at http://www.youtube.com/watch?v=0j9w5brozV4 (last visited November 11, 2013), Defendants made the following misrepresentations about the Bair Hugger:

a. "3M Bair Hugger forced-air warming does NOT influence the effectiveness of laminar flow system";

b. Claims by conductive warming manufacturers that Bair Hugger disrupts laminar flow are "inaccurate and irresponsible";

c. Laminar airflow is "stronger" than the convective currents created by the Bair Hugger.

67. The preceding statements are not new claims from Defendants. They have been making these intentionally misleading statements to the public and medical community for years. In an advertisement that appeared in medical publications as early as 2010, available online at http://www.fawfacts.com/_asset/zn062p/AJIC.pdf (last visited July 17, 2015), Defendants made the following false and deliberately misleading claims:

a. "While simple logic makes it clear that forced air warming has no impact on laminar conditions, science also supports this. A forced air warming blanket delivers less than one percent of the airflow of a laminar flow system and therefore is unable to affect laminar flow ventilation systems."

68. Scientific research published both before and after this statement has demonstrated any such assertion to be false. Not only does the exhaust generated by the Bair Hugger create convective airflow patterns that disrupt the unidirectional airflow of the operating theater, but the mobilization and release of built-up pathogenic contaminants inside the device increase the risk of surgical site infections among all patient populations.

69. In the face of that research and safer alternative designs, Defendants continue to extol the benefits of the Bair Hugger to the public and healthcare providers. In a communication that appeared in HEALTHCARE PURCHASING NEWS in July 2012, for instance, Defendants' public relations and communications specialist Greta Deutsch averred: "[S]ome conductive-warming manufacturers have alleged that forced-air warming increases bacterial contamination of operating rooms or interrupts laminar airflow. These accusations have no factual basis."[10]

70. Consistent with Defendants' prior misrepresentations, Ms. Deutsch's assertion ignored numerous studies documenting the adverse effects of the Bair Hugger.

71. These peer-reviewed publications include but are not limited to:

a. Albrecht, M., et al. Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. Am J Infect Control 2011;39:321-28;

b. Leaper, D., et al. Forced-air warming: A source of airborne contamination in the operating room? Orthopedic Rev. 2009;1(2):e28;

c. McGovern, P., et al. Forced-air warming and ultra-clean ventilation do not mix. J Bone and Joint Surg-Br. 2011;93(11):1537-44;

d. Legg, A., et al. Do forced air patient-warming devices disrupt unidirectional downward airflow? J Bone and Joint Surg-Br. 2012;94-B:254-56;

e. Belani, K., et al. Patient warming excess heat: The effects on orthopedic operating room ventilation performance. Anesth Analg. 2013;117(2):406-11;

[10] See Cantrell, Susan, Normothermia Reduces Infection, HEALTHCARE PURCHASING NEWS (July 2012), http://www.hpnonline.com/inside/2012-07/1207-OR-TempMgmt.html.

f. Dasari, K., et al. Effect of forced air warming on the performance of operating theatre laminar flow ventilation. Anaesthesia 2012;67:244- 49;

g. Avidan, M., et al. Convection warmers—not just hot air. Anaesthesia 1997;52:1073-76;

h. Bernards, A., et al. Persistent Acinetobacter baumannii? Look inside your medical equipment. Infect Control Hosp Epidemiol. 2004;25:1002-04;

i. Brandt, S., et al. Resistive-polymer versus forced-air warming: comparable efficacy in orthopedic patients. Anesth Analg. 2010;110:834-38;

j. Kimberger, O., et al. Resistive polymer versus forced-air warming: comparable heat transfer and core rewarming rates in volunteers. Anesth Analg. 2008;107:1621-26;

k. Legg, A., et al. Forced-air patient warming blankets disrupt unidirectional airflow. Bone Joint J. 2013;95-B:407-10;

l. Matsuzaki, Y., et al. Warming by resistive heating maintains perioperative normothermia as well as forced air heating. Bn J Anaesth. 2003;90:689-91;

m. Negishi, C., et al. Resistive-heating and forced-air warming are comparably effective. Anesth Analg. 2003;96:1683-87;

n. Ng, V., et al. Comparison of forced-air warming and electric heating pad for maintenance of body temperature during total knee replacement. Anaesthesia 2006;61:1100-04;

o. Reed, M., et al. Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions. Am Assoc Nurse Anesth. J 2013;81:275-80;

p. Sigg, D.C., et al. The potential for increased risk of infection due to the reuse of convective air-warming/cooling coverlets. Acta Anaesthesiol Scand. 1999;43:173-76;

q. Wood, A., et al. Infection control hazards associated with the use of forced-air warming in operating theatres. J Hosp Infect. 2014;1-9.

72. Publication of the foregoing studies should have prompted Defendants to redesign or discontinue the Bair Hugger, or at the very least to warn about the known risk of bacterial contamination associated with Bair Hugger use. Instead, Defendants made further misrepresentations and “doubled down” on their efforts to promote the device.

73. Plaintiffs’ physicians relied upon the above misrepresentations to Plaintiffs’ detriment. Any reasonable and competent physician would not have used a Bair Hugger in an orthopedic implant surgery if he or she were fully apprised of the risks of doing so.

74. Through misrepresentations to the public, the medical community, and the FDA, Defendants actively concealed the fact that the Bair Hugger increases the risk of infection in all types of surgeries, especially orthopedic implant surgeries.

75. Plaintiffs and their physicians were therefore unaware and could not have reasonably known or have learned through reasonable diligence of the significantly increased risk of infection associated with the Bair Hugger.

76. As a direct and proximate cause of Defendants’ wrongful conduct in designing, developing, testing, packaging, manufacturing, promoting, marketing, leasing, distributing, suppling, and/or selling this dangerous product, Plaintiffs have been damaged.

CLAIMS FOR RELIEF

COUNT I - NEGLIGENCE

77. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

78. Defendants designed, developed, tested, manufactured, assembled, inspected, packaged, promoted, marketed, designed, advertised, leased, supplied, and/or sold the Bair Hugger to physicians, healthcare providers, and consumers.

79. At all times relevant to this action, Defendants had a duty to perform each of the foregoing functions with reasonable and due care for the safety and well-being of patients, including Plaintiffs, who were subject to the Bair Hugger during their surgeries.

80. Defendants also had a duty to warn all healthcare providers, including Plaintiffs' physicians, along with all consumers, including Plaintiffs, of the risks, dangers, and adverse side effects associated with the Bair Hugger.

81. Based on the following non-exhaustive list of particulars, Defendants knew or reasonably should have known that the Bair Hugger was unreasonably dangerous and defective when used as directed, intended, and designed:

   a. When hot air from the Bair Hugger escapes and is pushed down to the floor of the operating theater, the hot air picks up bacteria and other pathogens from the floor. When the still warmer air begins to rise after leaving the air current caused by the Bair Hugger, bacteria from the floor of the operating theater are deposited onto the surgical site.

   b. The Bair Hugger collects bacteria and other infectious pathogens in its internal airflow pathways. These pathogens are expelled from the disposable warming blanket and into the operating theater, dramatically increasing the risk of the patient developing an infection.

82. Upon information and belief, Defendants failed to exercise reasonable and due care under the circumstances and therefore breached this duty in the following ways:

a. Defendants failed to properly and thoroughly test the Bair Hugger before releasing the device to market;

b. Defendants failed to properly and thoroughly analyze the data resulting from pre-market testing of the Bair Hugger;

c. Defendants failed to conduct sufficient post-market testing and surveillance of the Bair Hugger;

d. Defendants designed, manufactured, marketed, advertised, leased, distributed, and sold the Bair Hugger to consumers, including Plaintiffs and their physicians, without an adequate warning of the significant and dangerous risks of the device and without proper instructions to avoid the harm which could foreseeably occur as a result of using the device;

e. Defendants failed to exercise due care when advertising and promoting the Bair Hugger;

f. Defendants failed to fulfill the standard of care required of a reasonable and prudent manufacturer of surgical products, specifically including products such as the Bair Hugger; and

g. Defendants negligently continued to manufacture, market, advertise, and distribute the Bair Hugger after Defendants knew or should have known of its adverse effects and/or the availability of safer designs.

83. As designers, developers, manufacturers, inspectors, advertisers, distributors, suppliers, and sellers of the Bair Hugger, Defendants had superior knowledge of the Bair Hugger and owed a duty of care to Plaintiffs and numerous other customers.

84. It was foreseeable that Defendants' actions, omissions, and misrepresentations would lead to severe, permanent, and debilitating injuries to Plaintiffs.

85. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as set forth in the Prayer for Relief.

COUNT II – STRICT LIABILITY

86. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

87. Defendants designed, manufactured, distributed, marketed, leased, supplied, and/or sold the Bair Hugger in a defective and unreasonably dangerous condition.

88. The propensity of the Bair Hugger to cause convection currents that disrupt the downward airflow of the operating theater makes the device both dangerous when used in the way it is ordinarily used and far more dangerous than reasonably contemplated by those who regularly purchase the device and have ordinary knowledge common to the community as to the characteristics of the device, including Plaintiffs and their physicians.

89. The propensity of the Bair Hugger's internal airflow pathways, including its non-HEPA compliant intake filter, to become contaminated with bacteria and other harmful pathogens also makes the Bair Hugger both dangerous when used in the way it is ordinarily used and far more dangerous than reasonably contemplated by those who regularly purchase the device, including Plaintiffs and their physicians.

90. In addition, the problems associated with cleaning and decontaminating the inside of the device, along with the lack of an outlet filter that could prevent the emission of contaminants into the operating theater, makes the Bair Hugger both dangerous when used in the way it is ordinarily used and far more dangerous than reasonably contemplated by those who regularly purchase the device, including Plaintiffs and their physicians.

A. Strict Liability – Failure to Warn

91. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

92. Defendants designed, manufactured, inspected, labeled, leased, distributed, marketed, sold, and otherwise released the Bair Hugger into the stream of commerce.

93. In doing so, Defendants directly advertised or marketed the Bair Hugger to the FDA, health care professionals, and consumers or persons responsible for consumers.

94. Defendants thus had a duty to warn of the risks associated with the device.

95. Defendants failed to adequately warn health care professionals and the public, including Plaintiffs and their physicians, about the true risks of the Bair Hugger, including that the device would release contaminated air into the surgical field and that the vented heat from the device would mobilize contaminated air from non-sterile areas of the operating theater to the surgical site, causing infections among all Plaintiffs.

96. Had Defendants provided timely and reasonable warnings regarding the safety and efficacy of the Bair Hugger, those warnings would have been heeded and no healthcare professional, including Plaintiffs' physicians, would have used the Bair Hugger and no patient or consumer, including Plaintiffs, would have allowed use of the device.

97. Defendants' failure to provide timely and reasonable warnings, instructions, and information regarding the Bair Hugger rendered the device unreasonably dangerous and defective.

98. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for

hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as set forth in the Prayer for Relief.

B. Strict Liability – Defective Design and Manufacture

99. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

100. While engaged in the manufacture and sale of the Bair Hugger, Defendants manufactured and sold the device to Plaintiffs, Plaintiffs' physicians, and other consumers within the steam of commerce.

101. Defendants intended and expected that the Bair Hugger would reach Plaintiffs in the condition in which the device was originally manufactured and/or sold.

102. In view of the utility of the device and the risk involved in its use, the design of the Bair Hugger and/or its component parts makes the product unreasonably dangerous.

103. At all times relevant to this action, an economically and technologically feasible and safer alternative design existed for the Bair Hugger, including but not limited to airflow-free warming technologies, which in reasonable medical probability would not have impaired the utility of the design and would have prevented or significantly reduced the risk of Plaintiffs' infections and subsequent injuries.

104. The Bair Hugger is thus defective in design as it is not reasonably fit, suitable, or safe for its intended purpose and its foreseeable risks exceed the benefits of its design.

105. The defective condition of the Bair Hugger made it unreasonably dangerous.

106. The Bair Hugger was expected to and did reach Plaintiffs without substantial change in the condition in which it was designed, manufactured, labeled, marketed, distributed, leased, sold, and otherwise released into the stream of commerce.

107. Although Defendants knew or should have known of the risks associated with the use of the Bair Hugger, as well as the defective nature of the device and the availability of safer alternative designs, Defendants have continued to design, manufacture, distribute, market, promote, distribute, lease, supply, and sell the Bair Hugger so as to maximize sales and profits at the expense of public health and safety, in conscious disregard of the foreseeable harm caused by this device.

108. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as set forth in the Prayer for Relief.

COUNT III – BREACH OF EXPRESS WARRANTY

109. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

110. Defendants expressly represented to Plaintiffs, other consumers, and the medical community that the Bair Hugger was safe and fit for its intended purposes and that it was of merchantable quality, adequately tested, and did not produce negative side effects.

111. Although Plaintiffs, other consumers, and the medical community relied upon Defendants' express representations, as set forth above, the Bair Hugger does not conform to any of those representations because the device is not safe and causes serious and deleterious side effects, including severe and permanent injuries, to innocent consumers.

112. At all relevant times, the Bair Hugger did not perform as safely as an ordinary consumer would expect or when used as intended or in a reasonably foreseeable manner.

113. Plaintiffs and their physicians, by the use of reasonable care, could not have discovered that Defendants breached their warranty or the danger in using the Bair Hugger.

114. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death,

aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as set forth in the Prayer for Relief.

COUNT IV – BREACH OF IMPLIED WARRANTY

115. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

116. Defendants designed, manufactured, inspected, labeled, leased, distributed, marketed, sold, and other otherwise released the Bair Hugger into the stream of commerce.

117. Defendants knew of the use for which the Bair Hugger was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

118. Defendants were aware that consumers, including Plaintiffs, would use the Bair Hugger for treatment in conjunction with orthopedic surgical procedures.

119. Plaintiffs were in privity with Defendants at all relevant times.

120. The Bair Hugger was expected to reach and did in fact reach consumers, including Plaintiffs, without substantial change in the condition in which the device was originally designed, manufactured, and sold by Defendants.

121. Defendants represented through their labeling, advertising, marketing materials, presentations, publications, and regulatory submissions that the Bair Hugger was safe

and, upon information and belief, fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Bair Hugger.

122. Defendants represented through their labeling, advertising, marketing materials, presentations, publications, and regulatory submissions that the Bair Hugger was safe and, upon information and belief, fraudulently withheld and concealed information about the substantial risks of serious injury associated with using the Bair Hugger.

123. Defendants represented that the Bair Hugger was more efficacious than other alternative devices and, upon information and belief, fraudulently concealed information regarding the true efficacy of the device.

124. In reliance upon Defendants' implied warranties, Plaintiffs and their physicians used the Bair Hugger as prescribed and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendants.

125. Plaintiffs, other consumers, and the medical community also reasonably relied upon the judgment and sensibility of the Defendants to sell the Bair Hugger only if the product was of merchantable quality and safe and fit for its intended use.

126. In violation of the following statutes, Defendants breached their implied warranty to Plaintiffs in that the Bair Hugger was not adequately tested and was not of merchantable quality, safe, or fit for its foreseeable and reasonably intended use:

a. Mo. Rev. Stat. §§ 400.2-314, et seq.;

b. Kan. Stat. Ann §§ 84-2-314, et seq.;

c. Ohio Rev. Code Ann. §§ 1302.27, et seq.;

d. Tex. Bus. & Com. Code §§ 2.314, et seq.;

127. Plaintiffs and their physicians, by the use of reasonable care, could not have discovered that Defendants breached their warranty or the danger in using the Bair Hugger.

128. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as set forth in the Prayer for Relief.

COUNT V – VIOLATION OF MISSOURI'S CONSUMER PROTECTION LAW

129. Plaintiffs restate the allegations set forth above as if fully rewritten herein, and further alleges as follows:

130. The Defendant has violated and continues to violate Missouri Consumer Protection statutes, Mo. Ann. Stat. §§ 407.010 *et seq*.

131. The Defendant is a corporation who intentionally sells merchandise, including the Bair Hugger, to consumers, including consumers in Missouri. The Defendant made false statements in advertisements for the Bair Hugger, in violation of Mo. Ann. Stat. §§ 407.010 *et seq*.

132. In advertising the Bair Hugger through various means in Missouri, including but not limited to television, radio, internet, the products label, pamphlets and letters, the Defendant made material assertions, representations, or statements of fact which are untrue, deceptive, or misleading.

133. Similarly, the Defendant also acted with, used, or employed fraud, false pretense, false promise, misrepresentation, misleading statements or deceptive practices with the intent that consumers, including Plaintiffs, rely on said statements or actions in connection with the sale of the merchandise, in violation of Mo. Ann. Stat. §§ 407.010 *et seq*.

134. Defendant violated the Missouri consumer protection laws through, *inter alia*, the following:

a. Representing through statements and advertisements that the Bair Hugger has approval, characteristics, uses, or benefits that it does not have;

b. Representing through statements and advertisements that the Bair Hugger and its filtration system is of a particular standard, qualify, or grade when it differs materially from that representation;

c. Representing through statements and advertisement that the Bair Hugger has uses, benefits, or characteristics that have been otherwise proven incorrect;

d. Falsely stating, knowingly or with reason to know, that services or repairs are not needed.

135. As a direct and proximate result of the Defendant's actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional, extensive treatment. Consequently, Plaintiffs have suffered damages and incurred and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered and will continue to suffer diminished capacity for the enjoyment of life, a diminished qualify of life, increased risk of premature death, aggravation of preexisting conditions and activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications and supplies. Plaintiff has incurred and will continue to incur mental and physical pain and suffering and loss of wages and wage-earning capacity.

136. The Defendant's conduct as described above was committed with knowing, conscious, wanton, willful and deliberate disregard for the value of human life and the rights and safety of consumers such as the Plaintiffs. Defendant's conduct warrants, if allowed by the Court upon motion, an award of punitive damages against Defendant in an amount appropriate to punish the Defendant and deter them from similar conduct in the future.

COUNT VI – VIOLATION OF THE MINNESOTA PREVENTION OF CONSUMER FRAUD ACT

137. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

138. The Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F.69, subd. 1, makes it unlawful for any "person" to engage in fraud or to make "false

pretense[s], false promise[s], misrepresentation[s], misleading statement[s] or deceptive practices, with intent that others rely thereon in connection with the sale of any merchandise."

139. The Bair Hugger qualifies as "merchandise" within the meaning of the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F.68, subd. 2.

140. Defendants qualify as "persons" within the meaning of the Minnesota Prevention of Consumer Fraud Act, Minn. Stat. § 325F.68, subd. 3.

141. As previously alleged, Defendants acted with, used, or employed fraud, false pretense, false promise, misrepresentation, misleading statements, and/or other deceptive practices with the intent that consumers, including Plaintiffs and/or their physicians, rely on said statements or actions in connection with the sale of the Bair Hugger.

142. Specifically, Defendants violated § 325F.69 through the following:

a. Representing through statements and advertisements that the Bair Hugger has approval, characteristics, uses, or benefits that it does not have;

b. Representing through statements and advertisements that the Bair Hugger and its filtration system is of a particular standard, quality, or grade when it differs materially from that representation;

c. Representing through statements and advertisements that the Bair Hugger has uses, benefits, or characteristics that have been otherwise proven incorrect; and

d. Falsely stating, knowingly or with reason to know, that services or repairs to the Bair Hugger are not needed.

143. Upon information and belief, Defendants knew that these representations were false when they made them, thus intending to defraud Plaintiffs by inducing them and their physicians to purchase the Bair Hugger.

144. Plaintiffs and their physicians were induced by those misrepresentations, causing them to purchase the Bair Huger instead of safer alternative warming devices.

145. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

146. Where, as here, Plaintiffs' claims inure to the public benefit, Minnesota's private-attorney general statute, Minn. Stat. § 8.31, allows Plaintiffs to bring a civil action to recover damages, together with costs and disbursements, including attorneys' fees.

WHEREFORE, by reason of such violation and pursuant to Minn. Stat. § 8.31, subd. 3a, and § 325F.67, Plaintiffs are entitled to recover all of the monies paid for the product; to be compensated for the cost of the medical care arising out of the use of the produc; and to recover any and all consequential damages recoverable under the law including but not limited to both past and future medical expenses; past wage loss; loss of future earning capacity; and, past and future pain, suffering, disability, and emotional distress. Plaintiffs are entitled to seek compensatory damages, attorneys' fees, injunctive and equitable relief, and other remedies as determined by the Court pursuant to Minn. Stat. §§ 8.31, 325F.67.

COUNT VII – VIOLATION OF THE MINNESOTA DECEPTIVE TRADE PRACTICES ACT

147. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

148. The Minnesota Deceptive Trade Practices Act, Minn. Stat. § 325D.44, provides a private cause of action when a business causes a likelihood of confusion as to the certification of goods or services; represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have; represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another; advertises goods or services with intent not to sell them as advertised; or engages in any other conduct which creates a likelihood of confusion among consumers.

149. Defendants caused a likelihood of confusion as to the quality, benefit, sponsorship, approval, characteristics, and use of the Bair Hugger in the following ways:

a. Representing through statements and advertisements that the Bair Hugger has approval, characteristics, uses, or benefits that it does not have;

b. Representing through statements and advertisements that the Bair Hugger and its filtration system is of a particular standard, quality, or grade when it differs materially from that representation;

c. Representing through statements and advertisements that the Bair Hugger has uses, benefits, or characteristics that have been otherwise proven incorrect; and

d. Falsely stating, knowingly or with reason to know, that services or repairs to the Bair Hugger are not needed.

150. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

WHEREFORE, pursuant to Section 325D.45 of the Minnesota Trade Practices Act, Plaintiffs are entitled to injunctive relief, costs, and attorneys' fees, as requested below.

COUNT VIII – VIOLATION OF THE MINNESOTA UNLAWFUL TRADE PRACTICES ACT

151. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

152. Section 325D.13 of the Minnesota Unlawful Trade Practices Act states that "[n]o person shall, in connection with the sale of merchandise, knowingly misrepresent, directly or indirectly, the true quality, ingredients, or origin of such merchandise."

153. The Bair Hugger qualifies as "merchandise" within the meaning of the Minnesota Unlawful Trade Practices Act, Minn. Stat. § 325D.10.

154. Defendants qualify as "persons" within the meaning of the Minnesota Unlawful Trade Practices Act, Minn. Stat. § 325D.10.

155. As described in preceding paragraphs, Defendants did not disclose that the Bair Hugger would circulate contaminated air in the operating theater or that the vented heat from the Bair Hugger would mobilize contaminated air from the floor of the operating theater to the surgical site, causing serious infections among all Plaintiffs.

156. Rather than disclosing that information to Plaintiffs and their physicians, Defendants knowingly misrepresented the quality of the Bair Hugger in numerous ways:

a. Representing through statements and advertisements that the Bair Hugger has approval, characteristics, uses, or benefits that it does not have;

b. Representing through statements and advertisements that the Bair Hugger and its filtration system is of a particular standard, quality, or grade when it differs materially from that representation;

c. Representing through statements and advertisements that the Bair Hugger has uses, benefits, or characteristics that have been otherwise proven incorrect; and

d. Falsely stating, knowingly or with reason to know, that services or repairs to the Bair Hugger are not needed.

157. Defendants therefore knowingly misrepresented, in connection with the sale of the Bair Hugger, the true quality of the Bair Hugger.

158. Plaintiffs and their physicians were induced by those misrepresentations, causing them to purchase the Bair Hugger and use the device during their surgeries.

159. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

160. Where, as here, Plaintiffs' claims inure to the public benefit, Minnesota's private-attorney general statute, Minn. Stat. § 8.31, allows Plaintiffs to bring a civil action to recover damages, together with costs and disbursements, including attorneys' fees.

WHEREFORE, by reason of such violation and pursuant to Minn. Stat. § 8.31, subd. 3a, and § 325D.15, Plaintiffs are entitled to recover all of the monies paid for the product; to be compensated for the cost of the medical care arising out of the use of the product; and to recover any and all consequential damages recoverable under the law including but not limited to both past and future medical expenses; past wage loss; loss of future earning capacity; and, past and future pain, suffering, disability, and emotional distress. Plaintiffs are entitled to seek compensatory damages, attorneys' fees, injunctive and equitable relief, and other remedies as determined by the Court pursuant to Minn. Stat. §§ 8.31, 325D.15.

COUNT IX – VIOLATION OF THE MINNESOTA FALSE ADVERTISING ACT

161. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

162. The Minnesota False Advertising Act, Minn. Stat. § 325F.67, states that:

> Any person, firm, corporation, or association who, with intent to sell . . . anything offered by such person, firm, corporation, or association, directly or indirectly, to the public, for sale or distribution, or with intent to increase the consumption thereof, or to induce the public in any manner to enter into any obligation relating thereto, or to acquire title thereto, or any interest therein . . . places before the public, or causes, directly or indirectly, to be made, published, disseminated, circulated, or placed before the public, in this state, . . . an advertisement of any sort regarding . . . anything so offered to the public, for use, consumption, purchase, or sale, which advertisement contains any material assertion, representation, or statement of fact which is untrue, deceptive, or misleading, shall . . . be guilty of a misdemeanor, and any such act is declared to be a public nuisance and may be enjoined as such.

163. As described in preceding paragraphs of this Complaint, in advertising the Bair Hugger through various means in Minnesota, including but not limited to television, radio, internet, the products label, pamphlets, and letters, Defendants made material assertions, representations, or statements of fact which are untrue, deceptive, or misleading.

164. Defendants' campaign was widespread, reaching all corners of Minnesota.

165. Upon information and belief, Defendants knew that their assertions, representations, and/or statements of fact were false when they made them, thus intending to defraud Plaintiffs, other consumers, and the medical community by inducing them to purchase the Bair Hugger.

166. Plaintiffs and their physicians were induced by those misrepresentations, causing them to purchase the Bair Hugger and use the device during surgery.

167. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

168. Where, as here, Plaintiffs' claims inure to the public benefit, Minnesota's private-attorney general statute, Minn. Stat. § 8.31, allows Plaintiffs to bring a civil action to recover damages, together with costs and disbursements, including attorneys' fees.

WHEREFORE, by reason of such violation and pursuant to Minn. Stat. § 8.31, subd. 3a, and § 325F.67, Plaintiffs are entitled to recover all of the monies paid for the product; to be compensated for the cost of the medical care arising out of the use of the product; and to recover any and all consequential damages recoverable under the law including but not limited to both past and future medical expenses; past wage loss; loss of future earning capacity; and, past and future pain, suffering, disability, and emotional distress. Plaintiffs are entitled to seek compensatory damages, attorneys' fees, injunctive and equitable relief, and other remedies as determined by the Court pursuant to Minn. Stat. §§ 8.31, 325F.67.

COUNT X – CONSUMER FRAUD AND/OR UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

169. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

170. Certain Plaintiffs herein will bring a cause of action for consumer fraud and/or unfair and deceptive trade practices under applicable state law.

171. Defendants are on notice that such claims may be asserted by those Plaintiffs.

172. Plaintiffs purchased and used the Bair Hugger and suffered ascertainable losses as a result of Defendants' actions in violation of these consumer protection laws.

173. Had Defendants not engaged in the deceptive conduct described herein, neither Plaintiffs nor their physicians would have purchased and/or paid for the Bair Hugger; nor would Plaintiffs have incurred related medical costs and injuries from using the device.

174. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, monies from Plaintiffs and/or Plaintiffs' physicians for the device that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

175. Unfair methods of competition or deceptive acts or practices that were proscribed by law include the following:

a. Representing that goods or services have approval, characteristics, ingredients, uses benefits or quantities that they do not have;

b. Advertising goods or services with the intent not to sell them as advertised; and

c. Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

176. Plaintiffs were injured by the cumulative and indivisible nature of Defendants' conduct. Each aspect of Defendants' conduct was intended to artificially create sales of the Bair Hugger.

177. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, development, manufacture, promotion, and sale of products.

178. Defendants' deceptive, unconscionable, and/or fraudulent representations and material omissions to Plaintiffs and Plaintiffs' physicians constituted unfair and deceptive acts and trade practices in violation of the following consumer protection statutes:

a. Mo. Ann. Stat. §§ 407.010, et seq.;

b. Kan. Stat. Ann. §§ 50-623, et seq.;

c. Ohio Rev. Code Ann §§ 1345.01, et seq.;

d. Tex. Bus. & Com. Code Ann. §§17.41, et seq.;

179. Under the foregoing statutes, Defendants are the suppliers, manufacturers, advertisers, and sellers of the Bair Hugger, who are subject to liability under such legislation for unfair, deceptive, fraudulent, and unconscionable consumer sales practices.

180. The actions and omissions of Defendants are uncured or incurable.

181. On information and belief, Defendants had actual knowledge of the defective and dangerous condition of the Bair Hugger and failed to take any action to cure those conditions.

182. Plaintiffs and the medical community relied upon Defendants' misrepresentations and omissions in determining which patient warming device to use.

183. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

WHEREFORE, Plaintiffs request that they be granted relief against Defendants as set forth in the Prayer for Relief and as permitted by the aforementioned state laws.

COUNT XI – NEGLIGENT MISREPRESENTATION

184. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

185. Defendants negligently misrepresented the risks of use of the Bair Hugger in surgeries, particularly in surgeries of the kind that were performed on Plaintiffs.

186. These misrepresentations include but are not limited to the following particulars:

a. Defendants represented through labeling, advertising, marketing materials, presentations, publications, notice letters, and regulatory submissions that the Bair Hugger had been tested and found to be safe and effective for warming patients during orthopedic surgery; and

b. Defendants represented that the Bair Hugger was safer than other patient warming systems.

187. These misrepresentations, among others alleged herein, were made by Defendants with the intent to induce Plaintiffs and their physicians to use the Bair Hugger.

188. At the time of Defendants' misrepresentations and omissions, Plaintiffs and their physicians were ignorant of the falsity of the statements and believed them to be true.

189. Plaintiffs and their physicians reasonably relied upon Defendants' misrepresentations and omissions regarding the characteristics of the Bair Hugger.

190. Defendants therefore failed to exercise reasonable care in obtaining or communicating truthful and accurate information to Plaintiffs and their physicians.

191. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as set forth in the Prayer for Relief.

COUNT XII – FRAUDULENT MISREPRESENTATION

192. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

193. On information and belief, Defendants made fraudulent misrepresentations with respect to the Bair Hugger, including but not limited to the following particulars:

a. Defendants represented through labeling, advertising, marketing materials, presentations, publications, notice letters, and regulatory submissions that the Bair Hugger had been tested and found to be safe and effective for warming patients during orthopedic surgery; and

b. Defendants represented that the Bair Hugger was safer than other patient warming systems.

194. On information and belief, Defendants knew as early as 1997 that the Bair Hugger caused an increased risk of infection during surgery and that modifications they had made to the design of the Bair Hugger were contributing to the incubation and circulation of bacteria and other pathogens in and around the operating theater.

195. Despite that knowledge, Defendants continue to provide false information to Plaintiffs and Plaintiffs' physicians, in addition to the medical community, the FDA, and the public at large, about the safety and efficacy of the Bair Hugger, as detailed above.

196. On information and belief, Defendants knew that their representations were false, yet they willfully, wantonly, and recklessly disregarded their obligations to provide truthful representations regarding the safety and risks of the Bair Hugger to Plaintiffs and Plaintiffs' physicians.

197. On information and belief, the representations were made by Defendants with the intent that doctors and patients, including Plaintiffs and their physicians, rely on those representations.

198. Plaintiffs and their physicians did in fact rely on Defendants' representations.

199. In the absence of Defendants' representations, the Bair Hugger would not have been used in any implantation surgeries, including the surgeries at issue in this case.

200. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as set forth in the Prayer for Relief.

COUNT XIII – FRAUDULENT CONCEALMENT

201. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

202. On information and belief, Defendants fraudulently concealed information with respect to the Bair Hugger, including but not limited to the following particulars:

a. Defendants represented through labeling, advertising, marketing materials, presentations, publications, notice letters, and regulatory submissions that the

Bair Hugger had been tested and found to be safe and effective for warming patients during orthopedic surgery; and

b. Defendants represented that the Bair Hugger was safer than other patient warming systems.

203. On information and belief, Defendants knew as early as 1997 that the Bair Hugger caused an increased risk of infection during surgery and that modifications they had made to the design of the Bair Hugger were contributing to the incubation and circulation of bacteria and other pathogens in and around the operating theater.

204. Defendants had sole access to the material facts concerning the dangers and unreasonable risks of the Bair Hugger.

205. On information and belief, the concealment of information by Defendants about the risks of the Bair Hugger was intentional, and Defendants knew that their representations were false.

206. The concealment of information and the misrepresentations about the Bair Hugger were made by Defendants with the intent that doctors and patients, including Plaintiffs and their physicians, would rely on those misrepresentations and omissions.

207. Plaintiffs and their physicians did rely on Defendants' misrepresentations and omissions, and Plaintiffs were unaware of the substantial risks of the Bair Hugger.

208. As a direct and proximate result of Defendants' actions, omissions, and misrepresentations, Plaintiffs suffered infections, requiring additional surgical procedures to clean the infected areas and/or remove their implants. Plaintiffs have therefore suffered damages and will continue to incur medical expenses as a result of using the Bair Hugger. Plaintiffs have also suffered a diminished capacity for the

enjoyment of life, a diminished quality of life, increased risk of premature death, aggravation of preexisting conditions, activation of latent conditions, and other losses and damages. Plaintiffs' direct medical losses and costs include care for hospitalization, physician care, monitoring, treatment, medications, and supplies. Plaintiffs have incurred and will continue to incur mental and physical pain and suffering, along with loss of wages and wage earning capacity.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as set forth in the Prayer for Relief.

COUNT XIV – LOSS OF CONSORTIUM

209. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

210. Plaintiffs, PATRICK & VIRGINIA NARENS AND PATRICIA & GLENN WILLIAMS were at all times relevant, and continue to be, husband and wife.

211. As a result of the injuries and damages sustained by Plaintiffs, their spouses have suffered the loss of care, comfort, society, and affection from Plaintiffs.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as set forth in the Prayer for Relief.

COUNT XV – UNJUST ENRIGHMENT

212. Plaintiffs restate the allegations set forth above as if fully rewritten herein.

213. Defendants have enjoyed enormous revenues from sales of the Bair Hugger.

214. It is unjust to allow Defendants to earn revenues and retain the benefits and profits from the Bair Hugger while Plaintiffs suffered injuries and damages as stated herein.

WHEREFORE, Plaintiffs respectfully request that they be granted relief against Defendants as set forth in the Prayer for Relief.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants and each of them, individually and jointly and severally, and request:

1. Compensatory damages;
2. Pre-judgment and post-judgment interest;
3. Statutory damages and relief;
4. Costs and expenses of this litigation;
5. Reasonable attorneys' fees and costs as provided by law;
6. Equitable relief in the nature of disgorgement;
7. Restitution to remedy Defendants' unjust enrichment; and
8. All other relief as the Court deems necessary, just, and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of all claims in this Complaint so triable.

Respectfully Submitted,

Date: November 30, 2016

BROWN AND CROUPPEN, P.C.

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